PB89-126080

Guidance for the Reregistration of Pesticide Products Containing Hexazinone as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Sep 88

U.S. Department of Commerce
National Technical Information Service
NTIS

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

540/RS-88-081
September 1988

PB89-126080

Pesticides

EPA

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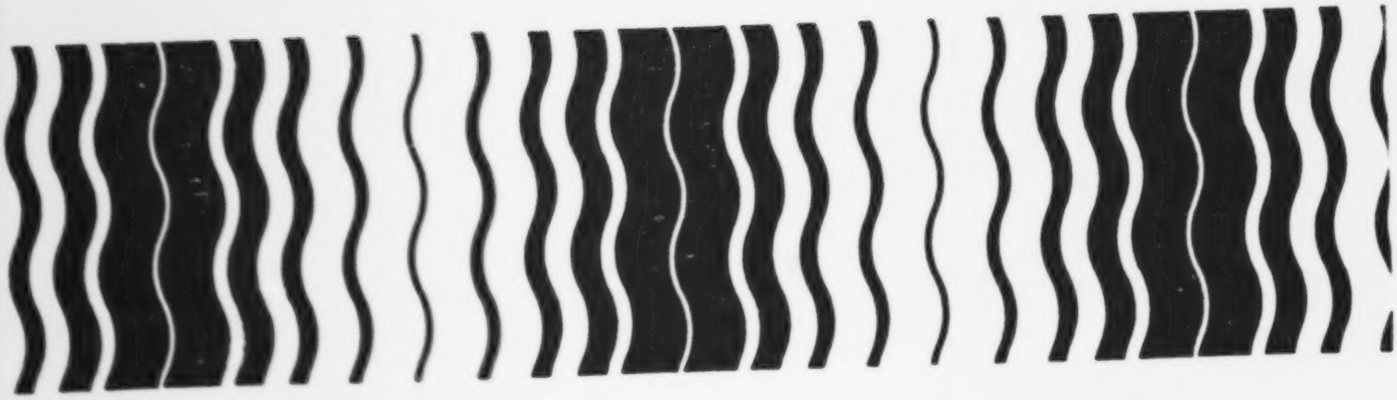

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U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL INFORMATION SERVICE
SPRINGFIELD, VA. 22161

OMB Control No. 2070-0057
Expires 11/89

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

HEXAZINONE

AS THE ACTIVE INGREDIENT

CASE NUMBER 0266

CAS (DOCKET) NUMBER 107201

SEPTEMBER 1988

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB89-126080/AS

4. Title and Subtitle
Guidance for the Reregistration of Pesticide Products
Containing HEXAZINONE as the Active Ingredient

5. Report Date September 1988

6.

7. Author(s)
EPA, Office of Pesticide Programs Registration Div.

8. Performing Organization Rept. No. 540/RS-88-081

9. Performing Organization Name and Address
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, S.W.
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address
Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manfacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:
Publicly Available

19. Security Class (This Report) Unclassified

20. Security Class (This Page) Unclassified

21. No. of Pages 110

22. Price

(See ANSI-Z39.18) See Instructions on Reverse OPTIONAL FORM 272 (4-77) (Formerly NTIS-35)

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.q., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

OES	Office of Endangered Species, U.S. Fish and Wildlife Service
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued in February 1982 the Agency described the available data supporting the registration of the chemical. The Agency concluded that additional data were necessary to fully evaluate the pesticide. The Agency also set out label language which the Agency concluded at that time were needed to ensure that products containing the pesticide remained in compliance with FIFRA.

The Agency has since received and reviewed the additional data and has revised its scientific and regulatory conclusions in light of those data, other information on the chemical, and expanded data requirements promulgated in 1984, at 40 CFR Part 158, for registration and reregistration of pesticides under FIFRA.

This revised Registration, which supersedes the earlier Standard, is the Agency's updated scientific assessment of the pesticide, and the data needed to support its continued registration. The Agency has also reassessed the tolerances for the pesticide; that reassessment is included in this Registration Standard.

The Agency has also reviewed the current labeling for products containing the pesticide, and has specified label revisions which are necessary to remain in compliance with FIFRA.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

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[1] The scientific reviews and Compendium of Uses may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Tel: (703) 487-4650.

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common Name: Hexazinone
Chemical Name: 3-cyclohexyl-6-dimethylamino-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione
Chemical Family: Triazines
CAS Registry Number: 51235-04-02
OPP (Shaughnessy) Number: 107201
Empirical Formula: $C_{12}H_{20}N_4O_2$
Trade Name: Velpar
Physical Characteristics: White Crystalline Solid
Molecular Weight: 252.3
Melting Point: 115-117 °C
Solublity: g/100 g solvent at 25 °C:
3.3 Water
388 Chloroform
265 Methanol
94 Benzene
83.6 Dimethylformamide
79.2 Acetone
38.6 Toluene
0.3 Hexane
Odor: Negligible
Vapor Pressure: 2×10^{-7} mmHg, 25 °C
Octanol/Water Partition Coefficient: 11.3
Specific Gravity: 1.25
Stability: Stable in aqueous solutions at pH 5, 7, 9, at temperatures up to 37 °C

B. USE PROFILE

Type of Pesticide: Hexazinone is a selective, triazine herbicide that is used to control grasses and broadleaf and woody plants.

Mechanism of Action: Hexazinone acts as a photosynthesis inhibitor. It is translocated primarily upward through the xylem tissues of the plant. It is readily absorbed through foliage and roots and usually shows a high degree of contact activity.

Registered Uses:

Terrestrial Food Crop use on alfalfa (including seed crop), fruit (blueberry, pineapple), sugarcane, pastures, rangeland, and fallowland.

Terrestrial nonfood crop use on bahiagrass and bermudagrass, noncrop areas (rights-of-ways, petroleum tank farms, storage areas, and industrial plant sites).

Aquatic nonfood crop use on drainage ditch banks.

Forestry use on Christmas tree plantations, conifers (nursery), conifer release and forest plantings.

Predominant Uses: Hexazinone use estimates are 33 percent on alfalfa, 31 percent in forestry, 29 percent in industrial areas, 4 percent on rangeland and pastures, and < 2 percent on sugarcane.

Formulations: Hexazinone is formulated as a technical, formulation intermediate, granular, pelleted/tableted, dry flowable, emulsifiable concentrate, soluble concentrate/liquid and ready-to-use liquid.

Methods of Application: Hexazinone may be applied either postemergence, preemergence, layby, directed spray, or basal soil treatment using ground equipment or where appropriate, broadcasted by aerial equipment.

Rates of Application:

Terrestrial food crop	- 0.22 - 6.0 lb ai/A
Terrestrial nonfood crop	- 0.67 - 13.5 lb ai/A
Aquatic nonfood crop	- 1.0 - 13.5 lb ai/A
Forestry	- 0.45 - 6.0 lb ai/A

C. BACKGROUND

Hexazinone was Federally registered in November 1975 for general weed control in noncropland areas. Uses in Christmas trees, reforestation areas, and woody plants were added in 1977. Sugarcane and alfalfa uses were added in 1980 and 1981, respectively. A Registration Standard for hexazinone was issued in February 1982. That document identified data gaps according to regulations then in place. After issuance of the 1982 Standard, new uses for hexazinone were established on blueberries, rangeland, pasture grasses, and pineapple. This document is a reevaluation of earlier studies and of those studies submitted since the issuance of the first Standard.

III. AGENCY ASSESSMENT

A. TOXICOLOGICAL ASSESSMENT

This section discusses data available to the Agency for the toxicological evaluation of hexazinone.

ACUTE TOXICITY STUDIES

Acute Oral

There was one acceptable study in male rats. An additional study in females is required. The oral LD_{50} of hexazinone technical was 1690 mg/kg for male Charles River CD rats with 95 percent confidence limits of 1560 to 1880 mg/kg. The study was classified as Core-Supplementary, Toxicity Category III, since females were not tested.

Acute Dermal

There was one acceptable study in male rabbits. An additional study in females will be required if the acute oral study indicates a sex difference or that females may be more sensitive than males. The dermal LD_{50} of hexazinone technical for male New Zealand White rabbits was greater than 5278 mg/kg. There were no deaths. The only toxic sign was mild erythema in one rabbit, which cleared by 24 hours. The study was classified as Core-Supplementary, Toxicity Category IV, since females were not tested.

Acute Inhalation

There was one acceptable study in male rats. An additional study in females will be required if the acute oral study indicates a sex difference or that females may be more sensitive than males. The acute inhalation LC_{50} of hexazinone technical in male Charles River CD rats for 1 hour of exposure was greater than 7.48 mg/L (gravimetric determination). There were no deaths. The toxic signs were salivation and irregular respiration. The study was classified as Core-Supplementary, Toxicity Category III, since females were not tested.

Primary Eye Irritation

There was one acceptable study. No additional studies are required. Nine rabbits received 0.1 mL of hexazinone technical in one eye each. The treated eyes of three of the rabbits were washed 20 seconds posttreatment. Observations were made at 1, 2, 3, 4, 7, 14, 21, and 28 days. At day 1, 6/6 animals of the unwashed group and 3/3 of the washed group had corneal opacity; 5/6 (unwashed) and 3/3 (washed) had iris irritation; 6/6 (unwashed) and 3/3 (washed) had conjunctivae redness, chemosis, and discharge. At day 7, 6/6 (unwashed) and 1/3 (washed) had corneal opacity; 2/6 (unwashed) iris irritation; 6/6 (unwashed) redness, chemosis, and discharge. At day 14, 4/6 (unwashed) and 1/3 (washed) had corneal opacity. At day 21, 4/6 (unwashed) had corneal opacity. At day 28, 4/6 (unwashed) had corneal opacity. The study was classified as Core-Guideline, Toxicity Category I. Hexazinone is considered to be corrosive, causing irreversible eye damage.

Primary Dermal Irritation

There was one acceptable study. No additional studies are required. Six rabbits received 0.5 g of hexazinone technical at two intact and two abraded skin sites per animal under occlusive wrap for 24 hours exposure. Observations were made at the end of the 24-hour exposure period and 2, 3, and 4 days after treatment. At 24 hours, 6/6 had erythema and 5/6 had edema. At 3 days, 3/6 had erythema and 1/6 had edema. The range of Primary Irritation Score was 0.50 to 1.50 (rating range is 0 - 4 (4 being severe)). The study was classified as Core-Guideline, Toxicity Category IV.

Dermal Sensitization

There was one unacceptable study in male guinea pigs. There was no skin irritation (erythema) on test sites. The study was classified as Core-Supplementary because the study design was inadequate and no positive control group was run. A repeat study is required.

SUBCHRONIC TOXICITY STUDIES

There were two acceptable studies reviewed. One study was in the rat and the other study was in the dog. No additional oral studies are required. A 21-day dermal study is required.

Sprague-Dawley (ChR-CD) albino rats were fed dietary levels of 0, 10, 50, and 250 mg/kg/day of hexazinone technical for 3 months. Criteria evaluated included toxic signs, body weight, food consumption, hematology, clinical chemistry, urinalysis, organ weights, and histopathology. The no observed effect level (NOEL) for the 90-day feeding study was 50 mg/kg. At the lowest effect level (LEL) of 250 mg/kg (highest dose tested (HDT)), there were decreased body weights in males (7%) and females (15%) in comparison to controls. There were no compound-related effects in mortality, toxic signs, food consumption, clinical pathology, organ weights, and histopathology. The study was classified as Core-Minimum.

In the dog study, beagle dogs 10 to 18 months of age, were fed dietary levels of 0, 5, 25, and 125 mg/kg/day of hexazinone technical for 3 months. Criteria evaluated included toxic signs, body weight, food consumption, hematology, clinical chemistry, urinalysis, organ weights, and histopathology. The NOEL was 25 mg/kg. At the LEL of 125 mg/kg (HDT), there was decreased body weight in both sexes, increased alkaline phosphatase in both sexes, decreased albumin/globulin values in both sexes, and increased absolute and relative liver weight in both sexes. There were no compound-related histopathological effects. The study was classified as Core-Minimum.

CHRONIC ORAL TOXICITY

One acceptable chronic feeding study in rats was submitted for technical hexazinone. This study was reviewed as a combined chronic toxicity/oncogenicity study. A data gap exists for a chronic nonrodent (dog) feeding study and the Agency is requiring submission of a dog study.

The combined chronic toxicity/oncogenicity rat feeding study was accepted as core-minimum data. Sprague-Dawley rats were fed dietary levels of 0 (control), 10, 50, and 125 mg/kg/day of hexazinone technical for 2 years. Criteria evaluated included toxic signs, morbidity, mortality, body weight, food consumption, hematology, urinalysis, biochemistry, organ weights, and histopathology. Statistical methods were not presented in the report.

There was increased survival over all test groups for male rats at 125 mg/kg at 2 years. The percent survival for male rats at 2 years was 31, 47, 39, and 69 percent for combined controls and low-, mid-, and high-dose groups, respectively. Survival at 2 years in female rats was comparable between control and treated groups. The systemic NOEL was 10 mg/kg. At the LEL of 50 mg/kg, females had a 5 percent decreased body weight and a slight decrease in food efficiency. At 125 mg/kg, there were significant toxic effects in both sexes. Males had a 12% body weight decrease, a 4% food consumption decrease, increased white blood cells and eosinophiles, alkaline urine and organ weight changes. Females had a 19% body weight decrease, slight food efficiency decrease, alkaline urine and organ weight changes.

ONCOGENICITY

One oncogenicity study in mice with technical hexazinone has been submitted. Additionally, an acceptable rat oncogencity study was submitted as part of a combined chronic toxicity/oncogenicity study. No additional oncogenicity studies are required at this time. A repeat mouse study, however, may be required at a later time.

In the combined chronic toxicity/oncogenicity rat feeding study (see Chronic Toxicity section above for details of the study), the oncogenic potential was negative up to and including 125 mg/kg (HDT). This dosage level was considered to be a maximum tolerated dose (MTD).

In the mouse study, CD-1 mice were fed diets containing 0, 30, 375, and 1500 mg/kg/day of technical hexazinone for 2 years. Criteria evaluated include toxic signs, morbidity, mortality, body weight, food consumption, hematology, organ weights, and histopathology.

The results of the mouse study were inconclusive due to a possible ambiguity in the classification of liver neoplasia (hyperplastic nodules). The systemic NOEL is 30 mg/kg. At the LEL of 375 mg/kg, there were increases in toxic signs, decreased body weight of both sexes, and increased histological effects in the livers of male mice. The 1500 mg/kg (HDT) level was the MTD because there were significant body weight decreases in both sexes, increased food consumption in both sexes, increase in mean absolute and relative liver weight in males, and increase in mean relative liver weight in females. Histologically, there were increased incidence of hepatocellular hypertrophy, focal necrosis, and hyperplastic nodules in male mice and hepatocellular hypertrophy in female mice. All control, low-, mid-, and high-dose group liver slides for both sexes are to be submitted to EPA for additional histopathological evaluation. This study is classified as Core-Supplementary pending Agency review of the slides.

Hexazinone's oncogenic potential will be reassessed based on all data on file with the Agency when the review of the slides from the mouse study is completed.

TERATOGENICITY

Three teratology studies were submitted. Two were in rats (one by gavage and one by diet) and the third was in rabbits (by gavage). There are no additional teratology studies required.

In the rat gavage study, Sprague-Dawley rats were administered technical hexazinone once daily by gavage, on days 7 to 16 of gestation, at doses of 0, 40, 100, 400, and 900 mg/kg/day. Antemortem criteria evaluated included toxic signs, morbidity, mortality, body weight, and food consumption. On gestation day 22, all remaining dams were sacrificed by CO_2 inhalation and examined grossly. Reproductive parameters, the weight of the liver, and gravid uterus were determined. Fetuses were sexed and examined for external, visceral, and skeletal abnormalities.

At 900 mg/kg/day (HDT), developmental toxicity was evidenced as decreased fetal body weight of both sexes, increased incidence, of fetuses with kidney anomalies, and an increased percentage of fetuses with retarded development (partial ossification). The NOEL for developmental toxicity was 100 mg/kg/day. At the LEL of 400 mg/kg/day, there was decreased female fetal body weight, marginally increased kidney anomalies, and increase in unossified sternebrae in fetuses.

The NOEL for maternal toxicity was 100 mg/kg/day. At the LEL of 400 mg/kg/day, there was decreased food consumption, increased relative liver weight, decreased body weight gain, and increased incidence of clinical signs. The study was classified as Core-Guideline.

In the rat dietary study, pregnant Sprague-Dawley rats were fed diets containing 0, 10, 50, and 250 mg/kg/day of hexazinone technical during days 6 to 15 of gestation. On day 21 of gestation, all dams were sacrificed by chloroform inhalation. Reproductive parameters were determined. Fetuses were sexed and examined for external, visceral, and skeletal abnormalities.

The developmental toxicity potential was negative up to 250 mg/kg (HDT) in the diet during days 6 to 15 of gestation. The NOEL for maternal toxicity was 50 mg/kg. At the LEL of 250 mg/kg, there was decreased body weight and increased incidence of partial resorptions in treated dams. The study was classified as Core-Supplementary since individual animal data were not provided and the study design was inadequate (test material administered in feed rather than by gavage).

In the rabbit study, New Zealand White rabbits were gavaged dailey with 0, 20, 50, and 125 mg/kg/day of technical hexazinone from day 6 through 19 of gestation. On day 29 of gestation, all surviving does were sacrificed. Reproductive parameters were recorded. Fetuses were examined for external, visceral, and skeletal abnormalities.

The NOEL for developmental toxicity was 50 mg/kg/day. The LEL was 125 mg/kg/day (HDT) and the effects were decreased fetal body weight and increased delayed ossification of skeletal extremities in fetuses. The maternal NOEL was 50 mg/kg/day. At the LEL of 125 mg/kg/day, there was decreased body weight, increased resorptions, and increased clinical signs. The study was classified as Core-Minimum.

REPRODUCTION

The Agency has reviewed one three-generation reproduction study in rats. Sprague-Dawley rats were fed dietary levels of 0, 10, 50, and 125 mg/kg/day of hexazinone technical through three generations with one litter per generation. The NOEL was 50 mg/kg/day. The LEL was 125 mg/kg/day (HDT) and the effect was decreased average weight of weanlings (day 21) in the F_{2a} and F_{3a} litters. There were no compound-related effects in fertility, gestation, viability, and lactation indices in the F_{1a}, F_{2a}, and F_{3a} litters. The study classification was Core-Supplementary. The deficiencies included (1) incomplete Material and Methods sections, (2) insufficient Summary Tables, (3) Clinical Observations data not provided, and (4) necropsy, organ weights, pup histopathology data, and statistical analyses data not provided. This study may be upgraded if a more complete report can be submitted.

MUTAGENICITY TESTING

An acceptable battery of mutagenicity studies has been submitted. No additional mutagenicity studies are required. Hexazinone has been determined as not a mutagen.

Gene Mutation

There was one acceptable gene mutation study in bacteria. Hexazinone technical was evaluated both with and without S-9 in five histidine-requiring strains of *S. typhimurium* at concentrations of 0, 400, 800, 1200, 1600, or 2000 ug/plate with activation and at concentrations of 0, 200, 400, 800, or 1000 ug/plate without activation. Positive controls were employed. The technical grade product was not mutagenic under conditions of the assay.

Chromosomal Aberration

The Agency has reviewed two chromosomal aberration assays both of which are acceptable. The first study evaluated hexazinone technical *in vitro* in the Chinese hamster ovary cells system both with and without S-9 treatment at dosages up to 19.82 mM without S-9 and up to 15.85 mM with S-9. Appropriate negative and positive controls were evaluated concurrently. Without S-9, hexazinone technical was *positive* at 15.85 mM.

In the second study, hexazinone technical was administered as a single oral dose to male and female Sprague-Dawley rats at 100, 300, and 1000 mg/kg. Positive controls were evaluated concurrently. Bone marrow was extracted from the femurs of each animal and slides of cells were prepared. The technical grade product did not induce chromosomal aberrations under the conditions of the assay.

Direct DNA Damage

Hexazinone technical was evaluated for unscheduled DNA synthesis at dosages ranging from 1 x 10^{-5} to 30 mM in primary rat hepatocytes obtained from the livers of 8-week-old Sprague-Dawley rats (200-300 g). Unscheduled DNA "repair" synthesis, evidenced by a net increase in black silver grains over the nucleus, was not increased by hexazinone technical. The study was acceptable.

METABOLISM

The Agency has reviewed one acceptable rat metabolism study. C^{14}-labeled hexazinone was used in the study. Three groups of male and female Sprague-Dawley rats were used. The rats received (a) a single 14 mg/kg dose of C^{14}-hexazinone without preconditioning; (b) a single 14 mg/kg dose of C^{14}-hexazinone (14 mg/kg) following a 3-week preconditioning period with 100 ppm cold hexazinone in the diet; and (c) a single high dose (1000 mg/kg) of C^{14}-hexazinone without preconditioning. After dosing, the rats were placed in individual metabolism cages. Urine and feces were collected, blood was drawn by cardiac puncture at sacrifice, and tissues were removed.

C^{14}-hexazinone was excreted as an average of 97 percent of the total dosed radioactivity via the urine (ca. 77%) and feces (ca. 20%) during the collection period and the results were comparable for each treatment regimen. Very low levels of radioactivity (ca. 0.2%) were detected in the GI tract, hide, excised organs, muscle, blood, and fat. Hexazinone was metabolized primarily by hydroxylation and demethylation resulting in eight major metabolites. No additional data are required.

HUMAN EXPOSURE

Hexazinone has not been reported to be associated with any death or hospitalized cases, either in national surveys or in California. In California, where physician-treated, occupational poisonings are reported, there have been no poisonings due to hexazinone since 1976. The voluntary accident reportings system (PIMS, Report Number 409, 1981) reported one accidental ingestion.

Protective clothing - Technical grade hexazinone is corrosive to the eye and causes irreversible eye damage. Use of protective goggles, face shield, or safety glasses are required for mixers, loaders, and applicators.

Reentry - Reentry data are not required. These data are required only when both the toxicity and the exposure criteria of 40 CFR 158.140 are met. Hexazinone is registered for use on blueberries, pineapples, and Christmas trees which are crops that require hand labor. However, hexazinone would not normally be applied either to the foliage of these crops or just prior to hand labor operations. Agency has not received adequate toxicological or epidemiological evidence that residues of hexazinone can cause adverse effects on persons entering treated sites.

B. OTHER SCIENCE FINDINGS

ENVIRONMENTAL FATE

Environmental fate data show that hydrolysis is not an important degradation pathway for hexazinone (less tha 20 percent of parent material had decomposed after an 8-week period, in the environmentally significant pH range 5 to 9).

While the photodegradation in water studies were not acceptable, there is indication that the presence photosensitizers contribute to the photodegradation of hexazinone. Studies must be performed using the full spectrum of natural sunlight. However, the major decomposition pathway for hexazinone appears to be microbial degradation.

Hexazinone is structurally related to triazine pesticides that are known to contaminate groundwater. While the mobility studies reviewed for this document are unacceptable they do indicate that hexazinone is mobile in soil and that the degree of mobility is dependent on soil type. Further, hexazinone is persistent in soils. Because no complete and acceptable data base is available to fully assess the ground-water contamination potential of hexazinone, the Agency will await submission of the required photodegradation, metabolism, mobility, dissipation, and groundwater monitoring studies before making a final assessment.

Fish accumulation studies showed that hexazinone does not have the tendency to accumulate in fish. A confined rotational crop study reviewed by the Agency was found not acceptable and must be repeated. Hexazinone's ditchbank use triggers the requirement for an irrigated crop study.

The Agency is requiring Droplet Spectrum and Spray Drift Field Evaluation tests because of the phytotoxicity of hexazinone, its aerial method of application, and the potential exposure of off-site plants to the pesticide.

ECOLOGICAL EFFECTS

Hexazinone is registered for numerous outdoor uses, including agricultural crops such as alfalfa and sugarcane, and nonagricultural uses such as forests and aquatic ditchbanks. Exposure to nontarget organisms can result from residues of direct applications, spray drift from treated areas, and rnoff from treated areas. Such exposures would be both acute and chronic. Due to the absence of appropriate environmental fate and nontarget organism toxicity data, a full ecological effects hazard assessment cannot be completed at this time.

Aquatic Organisms - The available information indicates that hexazinone is practically non-toxic to fish. The Guideline requirements for freshwater fish acute LC_{50} data with technical hexazinone have been met. The LC_{50} for freshwater fish results from two 96-hour studies using the technical grade material and the LC_{50} values are:

Species	% active	LC_{50} mg/l
Rainbow trout	97.5	>320
Bluefill sunfish	97.5	>370
Fathead minnow	97.5	=274
Bluegill sunfish	95.0	=505

Hexazinone is practically non-toxic to freshwater aquatic invertebrates (daphnids) with an EC_{50} value equal to 145.3 mg/l. With respect to toxicity to estuarine invertebrates, technical hexazinone is practically non-toxic to molluscs (48-hour EC_{50} >320 mg/l) and slightly toxic to crustaceans (96-hour LC_{50} = 78 mg/l for shrimp, 96-hour LC_{50} >1000 mg/l for fiddler crabs).

Terrestrial Organisms - The Guideline requirements for acute avian toxicity have been fulfilled. These data indicate that technical hexazinone is practically non-toxic on an acute oral basis to bobwhite quail (LD_{50} = 2258 mg/kg). Hexazinone was also considered practically non-toxic in two avian dietary toxicity studies (mallard LC_{50} >10,000 ppm and in bobwhite quail LC_{50} >5000 ppm).

There is insufficient information to assess hexazinone's toxicity to honeybees. As hexazinone has numerous outdoor uses which may result in bee exposure, data from a bee acute contact study are required.

Species Risk Assessment - Agricultural uses have application rates typically up to 1.5 lb ai/A and noncrop uses up to 12 lb ai/A. Maximum expected residues on avian foodstuffs at the highest label rates would not be expected to exceed 3000 ppm. The maximum residue in 6 inches of water resulting from a direct application at the maximum rate would be 8.8 ppm. With avian LC_{50}s greater than 5000 ppm and aquatic organism LC_{50}s greater than 100 ppm, hexazinone is not expected to pose an acute risk to nontarget fauna. Granular or pelleted products are not expected to pose an acute risk to avifauna as the acute oral LD_{50} is greater than 2000 mg/kg. The chronic hazard associated with these exposures cannot be determined.

Endangered Species - Because of hexazinone's expected toxicity to nontarget plant species (based on its label claims as a herbicide) and its intended use pattern, hexazinone has been identified by the Office of Endangered Species, U.S. Fish and Wildlife Service (FWS), as being likely to jeopardize endangered plant species when used on forests and/or rangeland. EPA is working with the FWS and other Federal and State agencies to implement labeling to protect endangered plant species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

Plant Protection - To determine the toxicity of hexazinone to non-target plants, the Agency is requiring seed germination/seedling emergence and vegetative vigor testing. As stated in the Environmental Fate Section, because hexazinone is also registered for aerial application, spray drift and droplet size studies are required.

PRODUCT CHEMISTRY

Although product chemistry data has been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. The Agency has also identifed that hexazinone could have nitrosamine contaminants due to the presence of certain chemicals in the manufacturing process. Therefore the Agency is requiring a discussion regarding the possible presence of nitrosamines from any manufacturing component or manufacturing process of hexazinone as well as chemical analysis of technical hexazinone for nitrosamine.

C. TOLERANCE ASSESSMENT

Tolerances have been established for residues of hexazinone in or on the raw agricultural commodities listed in 40 CFR 180.396. Tolerances for hexazinone are presently expressed in terms of the combined residues of hexazinone and its metabolites (calculated as hexazinone).

The existing residue chemistry data base was reviewed in the initial Hexazinone Registration Standard (February 1982) and found to be sufficient to assess the tolerances established at that time; no outstanding data gaps were identified. Subsequently, new uses of hexazinone have been registered and new Pesticide Assessment Guidelines (Subdivision O) have been issued. As a result, some of the conclusions made in the February 1982 Standard concerning the adequacy of data and conclusions about hexazinone have been reversed or altered. The following is the Agency's current position.

Metabolism - The nature of the residue in plants is adequately understood. However, the metabolism of hexazinone in animals is not adequately understood. Metabolism studies characterizing the total terminal residue of hexazinone in ruminants and poultry are required.

Analytical methodology - The 1982 Standard concluded that the GLC/nitrogen detector method was adequate for measuring hexazinone residues. This method has undergone successful FDA method validation. Residues of hexazinone and its metabolites occurring in or on raw agricultural commodities must be subjected to analysis by PAM Vol. I methods 211.1/ 212.1/252, 232.2, 232.4, and 242.2. These data are required because in some commodities the sum of the limits of the detection of hexazinone and its metabolites exceed the established tolerance for the combined residues of hexazinone and/or analysis of the metabolites is incomplete.

Residue data generated using the GLC/nitrogen detector method currently on file with the Agency will be reassessed on receipt of the aforementioned required data. Also, methods to be used in the future for data collection and enforcement will be determined on receipt of the requested metabolism and analytical method validation data.

Residue Storage Stability - The Agency does not have any data pertaining to the storage stability of hexazinone in commodities. When submitting this information to the Agency, storage conditions and intervals data must be supplied. This information must be accompanied by data depicting the percent decline in residues of hexazinone and its metabolites under the storage conditions and for the intervals specified. Samples bearing field-weathered residues or fortified samples of one representative commodity from each group must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested residue data.

As stated earlier, the nature of the residue in animals is not adequately understood. If the requested animal metabolism data indicate the presence of additional metabolites of toxicological concern, data depicting the stability of those residues in storage will be required.

Magnitude of Residues - The adequacy of established tolerances for hexazinone are based upon the Agency's evaluation of the existing data base. The Agency notes that the combined limits of detection for all metabolites of concern for several commodities (blueberries, sugarcane, and pineapple) exceed the established tolerances. Additional residue data are required to support the established tolerances for residues in or on blueberries, pineapples, and sugarcane.

There are no direct animal treatments for the herbicide hexazinone. At the present time, it is not possible to calculate the maximum expected intake of hexazinone residues by dairy cattle, beef cattle, poultry, or swine. Upon receipt of the storage stability and metabolism data, the nature of tolerances for hexazinone residues will be assessed and theoretical dietary exposures calculated.

Processing Data - Processing studies depicting the concentration of hexazinone residues in pineapple bran and juice and for sugarcane in molasses, bagasse, and refined sugar are required.

Pre-harvest Intervals - Pre-harvest intervals (PHI) that are based upon actual field residue data reflecting the maximum proposed use rates are needed for applications of hexazinone to alfalfa hay, pineapples, blueberries, and sugarcane.

Other Findings - The commodity entry "pineapple fodder" is inappropriate and should be deleted from the 40 CFR 180.396.

A tolerance must be proposed for pasture hay. Once this tolerance is established, it will allow the removal of the impractical restriction on labels against the cutting of hay.

All pertinent product labels must remove the impractical restriction on the feeding of alfalfa hay from the label. This is because the feeding of alfalfa hay is not under grower control.

Presently, no Codex MRLs exist for residues of hexazinone in or on any plant or animal commodity, therefore no compatibility problems exist between U.S. tolerances and Codex MRLs.

Dietary Assessment - The United States Department of Agriculture does not monitor residue data on hexazinone as part of the National Residue Program. The domestic and import samples collected by the FDA in FY 78-88 to date, and the Total Diet Market Baskets collected in April 1982 through April 1986 were not analyzed by methodology known to be capable of determining residues of hexazinone.

For the U.S. population, the theoretical maximum residue contribution (TMRC) from established tolerances was calculated to be 0.001587 mg/kg/day for a 60 kg person based on a 1.5 kg diet. This TMRC corresponds to 4.8% of the provisional acceptable daily intake (PADI). Utilizing the chronic toxicity study in rats, the PADI was established at 0.033 mg/kg/day, based on the NOEL of 10 mg/kg and a 300-fold safety factor. This is a PADI calculation because the chronic data base for hexazinone is not complete. The ADI will be calculated when the required data are received and evaluated.

IV. REGULATORY ASSESSMENT

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data on hexazinone, the Agency has made the following determinations:

1. The Agency will not place hexazinone in Special Review at this time.

Rationale: Based on the data available to the Agency, hexazinone has not met or exceeded any of the risk criteria specified in 40 CFR 154.7 for Special Review. There are presently no chronic toxicological concerns for exposure to hexazinone and there are sufficient data to indicate no unreasonable hazard to wildlife or endangered animal species. However, the Agency will delay a final determination until the chronic mouse study slides are reexamined. The Agency will evaluate potential risks as additional data become available and will consider additional regulatory action, if applicable.

2. The Agency is not classifying any hexazinone products or uses as Restricted Use.

Rationale: Based on data available to the Agency, hexazinone products have not met or exceeded any of the criteria specified in 40 CFR 162.11 which would indicate a need to restrict its use. When data become available to quantify the risks of hexazinone the Agency will reconsider its position on the classification of hexazinone.

3. The Agency will not register any significant new uses of hexazinone until product chemistry, toxicology, environmental fate, ecological effects and residue chemistry data required by this Standard have been submitted and found to be acceptable for assessing the proposed uses and demonstrate that the proposed uses will not result in unreasonable risks.

Rationale: The data gaps in these areas are such that registration of significant new uses of hexazinone should await submission and evaluation of the critical data required by this Standard.

4. The Agency is requiring ground water monitoring studies on hexazinone and its degradates to determine whether it contaminates ground water.

Rationale: Hexazinone and its degradates have been shown to be mobile in certain soils and persistent in water. Further, hexazinone is structurally related to other pesticides that do leach. The Agency does not feel that regulatory action, other than requiring retrospective ground water monitoring studies, is warranted.

5. The Agency will immediately review certain data as they are submitted.

Rationale: Because of concerns regarding potential risks from hexazinone use, the Agency believes it is essential that the following data be reviewed as they are received: the slides from the mouse oncogenicity study, the additional data on the reproduction study, and the acute oral study.

6. The Agency is requiring that a tolerance for pasture/rangeland hay be proposed so that the restriction against the cutting of hay from pasture/rangeland grass treated with hexazinone be removed from the label.

Rationale: Since a label restriction forbidding the cutting of hay from treated grasses is impractical, then a tolerance for such use must be established.

7. The Agency is requiring that the tolerance for alfalfa hay be revised in order to remove the label restriction against the feeding of alfalfa hay treated with hexazinone.

Rationale: A label restriction forbidding the feeding of alfalfa hay is impractical because such feeding is not under grower control. Therefore, the Agency is requiring that a revised tolerance for alfalfa hay be established and that an appropriate shorter PHI for hay be proposed.

8. The Agency is requiring that there be restrictions on the label forbidding the feeding of sugarcane forage to livestock and the grazing of domestic animals on conifer release and forest plantings areas.

Rationale: These restrictions must be on pertinent labels until appropriate tolerances are established.

9. In order to meet the statutory standard for continued registration, the Agency is requiring the use of certain minimum protective equipment for end-use products. The required labeling language is found in Section IV.D. of this document.

Rationale: Based on the primary eye irritation study, the Agency finds that this requirement is necessary to protect mixers, loaders, and applicators. The wearing of protective goggles, face shield, or safety glasses as specified in the required labeling will reduce exposure to hexazinone products and decrease the risk of adverse effects.

10. The Agency is not requiring a reentry interval at this time. However, the Agency reserves the right to call in reentry data if and when the required toxicology studies demonstrate a potential for chronic effects. The Agency believes that delaying entry into treated areas until sprays have dried, as specified on the label (see section IV. D.) will be sufficient.

Rationale: Reentry data are required under 40 CFR 158.140 only when both the toxicity and exposure criteria are met. Hexazinone does meet the exposure criteria of 40 CFR 158.140 in that it is registered for use on blueberries, pineapple, and Christmas trees (cultivation of these crops require extensive hand labor). However, hexazinone is not applied either to the foliage or concurrently when hand labor is required. The Agency has not received adequate toxicological or epidemiological evidence that residues of this pesticide can cause adverse effects on persons entering treated sites.

11. The Agency is requiring submission of droplet spectrum and spray drift field evaluation tests.

Rationale: The Agency is requiring these tests because of the phytotoxicity of hexazinone, its methods of application (aerial), and the likely exposure of off-site plants to the pesticide.

12. The Agency has determined that "pineapple fodder" must be deleted from the tolerance listing for hexazinone in 40 CFR 180.396.

Rationale: The commodity "pineapple fodder" is inappropriate because it is not a raw agricultural commodity.

13. The Office of Endangered Species (OES) in the U.S. Fish and Wildlife Service has determined that certain uses of hexazinone may jeopardize the continued existence of endangered plant species or critical habitat of certain endangered animal species. EPA is developing a program to reduce or eliminate exposure to these species to a point where use does not result in jeopardy, and will issue notice of any necessary labeling revisions when the program is developed.

No additional labeling is being required at this time. As explained below, labeling requirements issued in Pesticide Regulation (PR) Notices 87-4 and 87-5 have been withdrawn pending reissuance.

Rationale: In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to OES findings that certain pesticides, including this chemical, jeopardized the continued existence of endangered species. Those PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of the pesticide within the range of jeopardized endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988, the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species.

EPA is working to correct these errors prior to requiring labeling to protect endangered species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

14. While the data gaps are being filled, currently registered MPs and EPs containing hexazinone as an active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions described in this Standard.

Registrants must provide or agree to develop additional data, as specified in the Data Appendices of this document, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may choose not to cancel or withhold pesticide registrations if data are missing or inadequate (see FIFRA sections 3(c)(2)(B) and 3(c)(7)).

Issuance of this Registration Standard provides a mechanism for identifying data needs. When these data are submitted they will be reviewed and evaluated, after which the Agency will determine if additional regulatory action is warranted.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, manufacturing use and end use products must contain this Pesticide, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard. To conform to this Standard, manufacturing use end use products must contain this pesticide ingredient. Each formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients present in the product, as well as impurities found at levels greater than 0.1 percent.

Acute Toxicity Limits. The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide ingredient, provided the product is supported by appropriate acute toxicity data and the labeling for the product bears appropriate precautionary statements for the toxicity category in which the product is placed.

Use Patterns. To be registered under this Standard, manufacturing use products must be labeled for formulation into other manufacturing use products or into end use products bearing federally registered uses. The EPA Use Index (EPA Compendium of Acceptable Uses) (for availability, see page 1) lists all federally registered uses of this pesticide ingredient, as well as approved maximum application rates and frequencies.

The use patterns currently registered are terrestrial food and nonfood crop; aquatic nonfood crop; and forestry.

D. LABELING

In order to remain in compliance with FIFRA, all products must bear appropriate labeling as specified in 40 CFR 156.10 and this standard, or must be revised to conform to those specifications. Appendix II contains further information on label requirements.

Pesticide products containing this pesticide as an active ingredient may not be released for shipment by the registrant after September 1989 unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Registration Standard.

Pesticide products containing this pesticide as an active ingredient may not be distributed or sold after September 1990 unless the product bears amended labeling that complies with the requirements of this Standard.

In order to remain in compliance with FIFRA, the following information must appear on the labeling of all manufacturing-use (MPs) and end-use products (EPs).

1. Ingredient Statement. The ingredient statement for MPs and EPs must list the active ingredient as:

ACTIVE INGREDIENT
Hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-
triazine-2,4-(1H,3H)-dione)....................____%

2. Use Pattern Statements. All technical and manufacturing-use products must state that they are intended for formulation into end-use products registered for one or more of the uses listed in the EPA compendium of acceptable uses. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern, as provided in this Registration Standard.

3. The Following Must Appear on MP Labels

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

4. The Following Must Appear on EP Labels

In the Precautionary Statements

"Corrosive, causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Mixers, loaders, and applicators must wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

Environmental Hazards Statement

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

In the Directions for Use Section

"Do not enter or allow entry into treated areas until sprays have dried to perform hand tasks. A person may enter the areas to perform other tasks only if the person is wearing the personal protective eye equipment listed on the label."

As appropriate, the following grazing statements should appear in the label:

For sugarcane: "Do not feed sugarcane forage to livestock."

For conifer release and forest plantings (reforestation site preparation): "Do not graze domestic animals on treated areas within 30 days after treatment."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by an end use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to the data requirements in Table A.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will

submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Hexazinone Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately

notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are generally those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A

Generic Data Requirements for the Technical Grade of the Active Ingredient: Hexazinone[1]

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?[2]	Timeframe for Submission
Part 158 - Subpart C - Product Chemistry					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes[3]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes[4]	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes[5]	12 Months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	Yes	00104969	No	
63-3 - Physical State	TGAI	Yes	00104969	No	
63-4 - Odor	TGAI	Yes	00104969	No	
63-5 - Melting Point	TGAI	No		Yes[6,7]	6 Months
63-6 - Boiling Point	TGAI	No[8]		No	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00104969	No	
63-8 - Solubility	TGAI or PAI	Yes	00104969	No	

Table A

Generic Data Requirements for the Technical Grade of the Active Ingredient: Hexazinone[1]

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be submitted?[2]	Timeframe for Submission
Part 158 - Subpart C - Product Chemistry (continued)					
Physical and Chemical Characteristics (Cont'd)					
63-9 - Vapor Pressure	TGAI or PAI	Yes	00104969	No	
63-10 - Dissociation Constant	TGAI or PAI	No		Yes[6]	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes[6,9]	6 Months
63-12 - pH	TGAI	Partially	00118509	Yes[6,10]	6 Months
63-13 - Stability	TGAI	No		Yes[6]	6 Months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A		No	

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[1] The 98% T (EPA Registration No. 352-399) also serves as a manufacturing-use product. See also Table B, "Product Specific Data Requirements for Manufacturing-Use Products," for additional data requirements under Guidelines Reference Nos. 61-1, 62-2, 62-3, and 63-14 through 63-20 that are applicable to registered technical products.

[2] Although product chemistry data may have been submitted in the past, the Agency has determined that certain of these data must be resubmitted. New requirements have been introduced and previous submitted data must be updated. Therefore, many bibliographic citations for the old data are not applicable. However, data submitted in response to requests made in the interim Standard, dated February 1982, have been evaluated with regard to their adequacy in meeting the requirements of 40 CFR 158 Subpart C.

[3] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration

Table A
Generic Data Requirements for the Technical Grade of the Active Ingredient: Hexazinone[1] (Cont'd)

Part 158 - Subpart C - Product Chemistry Footnotes (Cont'd)

of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

4/A detailed discussion must be submitted for the 98% T of all impurities that are or may be present at ≥ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination that may occur during and after production. A discussion regarding the possible presence of nitrosamines or any other contaminant of toxicologic concern from any source in the product is also required.

5/Samples from five or more representative batches must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used. All nitrosamines must be identified and quantified (by methods sensitive to 1 ppm of N-nitroso contaminants) in six product samples; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. Upper limits must be provided and certified for all nitrosamines found.

6/Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158 Subpart C and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

7/The technical chemical is a solid at room temperature; therefore, data are required.

8/Data are not required because the technical product is a solid at room temperature.

9/Data required if the technical product is organic and nonpolar.

10/Data required if the test substance is soluble or dispersible in water.

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.240 Residue Chemistry					
171-2 - Chemical Identity[1]/					
171-3 - Directions for Use		(See Index)			
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA	Yes	00073047,00104846, 00126127	No	
171-4 - Nature of the Residue (Metabolism)					
- Livestock	PAIRA and plant metabolites	Partially	00104843	Yes[2,3]/	18 Months
171-4 - Residue Analytical Methods	TGAI and metabolites	Partially	00038868,00101574, 00126127	Yes[4]/	15 Months
171-4 - Storage Stability	TEP and metabolites	No		Yes[5]/	15 Months
171-4 - Magnitude of the Residue in Plants					
o Small Fruits and Berries					
- Blueberries	TEP	Partially	00101574	Yes[6]/	18 Months

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (Cont'd)					
o Grass Forage, Fodder and Hay					
- Grasses, Pastureland/ Rangeland	TEP	Partially	00138226	Yes[7/]	6 Months
o Nongrass Animal Feeds					
- Alfalfa Forage/ Hay	TEP	Partially	00118050	Yes[8/]	6 Months
o Miscellaneous Commodities					
- Pineapple	TEP	Partially	00126127	Yes[9,10/]	18 Months
				Yes[11/]	24 Months
- Sugarcane	TEP	Partially	00028733 00114039	Yes[12/]	18 Months
				Yes[13/]	24 Months
171-4 - Magnitude of the Residue in Milk/Meat/Poultry/Eggs					
- Milk, Fat, Meat Byproducts, and Meat of Cattle, Goats, Hogs, Horses, and Sheep	TGAI or plant metabolites	Partially	00028866	Yes[14/]	18 Months

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Milk/Meat/Poultry/Eggs (Cont'd)					
- Eggs, Fat, Meat Byproducts, and Meat of Poultry	TGAI or plant metabolites	Partially	00104845	Yes[14/]	18 Months

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1/The same chemical identity data are required under §158 - Subpart C, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

2/Metabolism studies must be submitted characterizing the total terminal residue of hexazinone in ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with ring-labeled $[^{14}C]$hexazinone fed in the diet at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected for analysis twice daily during the dosing period. Animals must be slaughtered within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using residue analytical methods developed for data collection and tolerance enforcement to ascertain that the methods are capable of adequately recovering and identifying all residues of concern.

3/Data depicting the nature of hexazinone residues in swine will also be required if the required metabolism studies with ruminants and poultry reveal that the metabolism of hexazinone in these animals differs from that in rats.

4/Residues of hezaxinone and its metabolites occurring in or on raw agricultural commodities must be subjected to analysis by PAM Vol. I methods 211./212.1/252, 232.4, and 242.2 (Multiresidue Protocols I-IV, available from the National Technical Information Service (NTIS) under Order No. PB 203734/AS).

5/Storage conditions and intervals must be submitted for all samples used to provide data reviewed or requested. This information must be accompanied by data depicting the percent decline in residues of hexazinone

Table A
Generic Data Requirements for Hexazinone

§158.240 Residue Chemistry Footnotes (Cont'd)

and its metabolites under the storage conditions and for the intervals specified. Samples bearing field-weathered residues or fortified samples of one representative commodity from each crop group must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested residue data. The storage intervals selected must allow for reasonable unforeseen delays in sample analysis. For additional guidance on conducting storage stability studies, the Registrant is referred to an August 1987 Position Document on the Effects of Storage on Validity of Pesticide Residue Data available from NTIS under Order No. PB88112362/AS.

6/Data must be submitted depicting combined residues of hexazinone and its metabolites (calculated as hexazinone) in or on mature blueberries harvested following broadcast application of (in separate tests) the 90% SC/L and 2 lb/gal EC formulations at 3 lb ai/A, applied with aerial and ground equipment, in separate tests, in a minimum of 5 and 40 gal/A, respectively. The registrant must propose amendments to all pertinent product labels that specify an appropriate PHI (based on the requested data). Tests must be conducted in ME and NH in which these uses are permitted (EPA SLN Nos. ME830003, ME830002, NH830007, and NH830008).

7/The registrant must amend all pertinent product labels to remove the impractical restriction against the cutting of grass hay. The registrant must also propose a tolerance for pasture hay supported by appropriate residue data.

8/The registrant must amend all pertinent product labels removing the impractical restriction on the feeding of hay because alfalfa hay may not be under grower control for 30 days. In addition, the registrant should propose an appropriate shorter PHI for hay which must be supported by appropriate residue data.

9/Data must be submitted depicting the combined residues of hexazinone and its metabolites (calculated as hexazinone) in or on pineapples harvested at normal crop maturity following the last of three postemergence directed spray applications of the 90% SC/L formulation at 1.8 lb ai/A/application, in 50 gal of water/A using aerial equipment. The registrant must amend all pertinent labels specifying a PHI which must be efficacious and supported by residue data. Tests must be conducted in HI which accounted for virtually all of the 1982 U.S. pineapple production (1982 Census of Agriculture, Vol. 1, Part 51, p. 383).

10/Data must be submitted depicting the combined residues of hexazinone and its metabolites (calculated as hexazinone) in or on pineapples harvested at normal crop maturity following multiple spot treatment applications of the 90% SC/L formulation at 1.8 lb ai/100 gal.

11/A processing study must be submitted depicting concentration of the combined residues of hexazinone and its metabolites (calculated as hexazinone) in bran and juice processed from pineapples bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerance must be proposed.

12/Data must be submitted depicting the combined residues of hexazinone and its metabolites (calculated as hexazinone) in or on sugarcane harvested at normal crop maturity following: (i) a single postemergence broadcast application of the 90% SC/L formulation at 3.6 lb ai/A, in 25 gal water/A using ground equipment, and in 5 gal/A using

Table A
Generic Data Requirements for Hexazinone

§158.240 Residue Chemistry Footnotes (Cont'd)

aerial equipment, followed by multiple spot treatments at 1.8 lbs ai/100 gal water (tests must be conducted in HI); (ii) a single postemergence application of the 90% SC/L formulation at 1.8 lb ai/A, in 25 gal water/A using ground equipment (tests must be conducted in FL); and (iii) a single layby application at 0.9 lb ai/A, in 5 gal water/A using aerial equipment (tests must be conducted in TX). The registrant must propose label amendments specifying a PHI which must be efficacious and supported by appropriate residue data.

13/A processing study must be submitted depicting concentration of the combined residues of hexazinone and its metabolites (calculated as hexazinone) in molasses, bagasse, and refined sugar processed from sugarcane bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

14/Data requirements regarding the magnitude of hexazinone residues in animal products will not be determined until all requested data regarding metabolism in animals and magnitude of residues in feed items have been received.

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Fill This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Avian Oral LD_{50}	TGAI	A,B,D,G	Yes	00078016	No	
71-2 - Avian Dietary LC_{50}						
a. Waterfowl	TGAI	A,B,D,G	Yes	00078029	No	
b. Upland Game Bird	TGAI	A,B,D,G	Yes	00078002	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B,D,G	No		No[1]	
71-4 - Avian reproduction	TGAI	A,B,D,G	No		Yes[2]	2 Years
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TGAI	A,B,D,G	No		No[3]	
Aquatic Organisms Testing						
72-1 - Freshwater Fish LC_{50}						
a. Warmwater	TGAI	A,B,D,G	Yes	00078044,00078040	No	
	TEP	D,G	No		Yes[4]	9 Months
b. Coldwater	TGAI	A,B,D,G	Yes	00078044	No	
	TEP	D,G	No		Yes[4]	9 Months
Aquatic Organisms Testing						
72-2 - Freshwater Invertebrate Acute EC_{50}	TGAI	A,B,D,G	Yes	00078042	No	
	TEP	D,G	No		Yes[4]	9 Months

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy this Data Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Aquatic Organisms Testing (Cont'd)						
72-3 - Estuarine and Marine Organism Acute EC_{50}						
a. Finfish	TGAI	A,B,D,G	No		No[5/]	
b. Crustacean	TGAI	A,B,D,G	Yes	00078018	No	
c. Oyster	TGAI	A,B,D,G	Yes	00078018	No	
72-4 - Fish and Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A,B,D,G	No		Yes[6/]	1 Year
72-5 - Aquatic Organism Accumulation	TGAI	D,G	Yes	00064265	No	
72-6 - Life-Cycle Tests with Fish	TGAI	D,G	No		No[7/]	
72-7 - Simulated or Actual Field Testing - Aquatic	TEP	A,B,D,G	No		No[7/]	
§158.540 Plant Protection						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		No[8/]	
122-1 - Vegetative Vigor	TGAI	B,D,G	No		No[8/]	
122-2 - Aquatic Plant Growth	TGAI	B,D,G	No		No[8/]	

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data) Be) Submitted?	Timeframe for Submission
§158.540 Plant Protection (Cont'd)						
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		Yes9/	9 Months
123-1 - Vegetative Vigor	TGAI	B,D,G	No		Yes9/	9 Months
123-2 - Aquatic Plant Growth	TGAI	B,D,G	No		Yes9/	9 Months
TIER III						
124-1 - Terrestrial Field	TGAI	B,D,G	No		Yes10/	
124-2 - Aquatic Field	TGAI	B,D,G	No		Yes10/	

1/Not generally required. Hexazinone does not trigger the special conditions necessary to require this study.
2/Avian reproduction testing is required to ascertain the chronic hazard of hexazinone residues expected to persist on avian foodstuffs.
3/Reserved pending receipt of avian reproduction and environmental fate requirements.
4/Required for formulated products (emulsifiable concentrates and solvent-based liquid formulations) used in forests and/or aquatic nonfood uses.
5/Waived based on demonstrated low toxicity to freshwater fish. TEP testing is reserved pending receipt of requested TEP testing on freshwater fish.
6/Required due to expected transport to and persistence in aquatic environments.
7/Reserved pending recept of outstanding aquatic data and environmental fate information.
8/These tests are not required since hexazinone is registered for use as a herbicide.
9/Required for all terrestrial nonfood, aquatic food and forest uses.
10/Higher tier testing is reserved pending receipt of the lower tier test results.

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additonal Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	PAIRA	A,B,D,G	Yes	00064260	No[1]	
Photodegradation						
161-2 - In Water	PAIRA	A,B,D,G	Partially	00064260	Yes[2]	9 Months
161-3 - On Soil	PAIRA	A	Partially	00064261	Yes[3]	9 Months
161-4 - In Air					No[4]	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	PAIRA	A,B,G	Partially	00064261	Yes[5]	27 Months
162-2 - Anaerobic Soil	PAIRA	A	Partially	00064261	Yes[6]	27 Months
162-3 - Anaerobic Aquatic	PAIRA	D,G	No		Yes[7]	27 Months
163-4 - Aerobic Aquatic	PAIRA	D	No		Yes[7]	27 Months
Mobility Studies						
163-1 - Adsorption/Desorption	PAIRA	A,B,D,G	Partially	00064262	Yes[8]	12 Months

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
Mobility Studies (Cont'd)						
163-2 - Volatility (Lab)					No[9/]	
164-3 - Volatility (Field)					No[9/]	
Dissipation Studies - Field						
164-1 - Soil	TEP	A,B	Partially	00064261	Yes[10/]	27 Months
164-2 - Aquatic (Sediment)	TEP	D	No		Yes	27 Months
164-3 - Forestry	TEP	G	Partially	00072664	Yes[11/]	27 Months
164-4 - Combination and Tank Mixes					No[12/]	
165-5 - Soil, Long-Term		A			Reserved[13/]	
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A			Reserved[14/]	
165-3 - Irrigated Crops		D	No		Yes[15/]	39 Months

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliogtaphic Citation	Must Additonal Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
Accumulation Studies (Cont'd)						
165-4 - In Fish	PAIRA	A,B,D,G	Yes	00064265	No	
165-5 - In Aquatic Nontarget Organisms			No		No[16]	
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,G	No		Reserved[17]	
132-1 - Soil Dissipation	TEP	NONE	No		No[18]	
133-3 - Dermal Exposure	TEP	A,B,G	No		Reserved[17]	
133-4 - Inhalation Exposure	TEP	A,B,G	No		Reserved[17]	
§158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B,D,G	No		Yes[19]	12 Months
201-1 - Drift Field Evaluation	TEP	A,B,D,G	No		Yes[19]	12 Months
§158.290 Environmental Fate						
Ground Water Monitoring Studies					Yes	39 Months
Human Exposure Assessment					Reserved[20]	24 Months

Table A
Generic Data Requirements for Hexazinone

§158.290 Environmental Fate Footnotes

1/Although the hydrolysis studies are not fully in accordance with current Subdivision N Guidelines, the reported results clearly indicate that hydrolysis is not an important degradation pathway for hexazinone and, therefore, the study can be accepted to fulfill data requirements for hydrolysis.

2/The photodegradation study includes studies in distilled water, in "standard reference water," and with river water with and without sediments. The studies were conducted under artificial sunlight (distilled water; standard reference water) and under natural sunlight (river water). Although the photodegradation study in water was considered acceptable to fulfill data requirements for the 1982 Registration Standard, it does not fulfill present Subdivision N Guidelines. Therefore, the studies are considered to partially fill data requirements as they indicate slow degradation in distilled water (about 20% in 8 weeks) at pH 6.1 (unbuffered) and that the presence of photosensitizers resulted in an increased rate of photodegradation.

3/The photodegradation study on soil was conducted under artificial sunlight conditions. This study is not acceptable under current Subdivision N Guidelines and, therefore, data requirements for photodegradation on soils are only partially fulfilled.

4/Not required because the vapor pressure of hexazinone is below 10^{-6} mmHg.

5/This study was conducted under greenhouse conditions. This study was considered acceptable to fulfill data requirements at the time the 1982 Registration Standard was prepared. However, under current Subdivision N data requirements for aerobic metabolism the studies are not considered fulfilled as the study is not considered acceptable under present Guidelines.

6/This study was conducted by flooding the soil incubated under aerobic conditions (in a greenhouse). Because the aerobic incubation phase of this study does not meet current Subdivision N Guidelines, the anaerobic studies are not acceptable and, therefore, do not fulfill data requirements. An acceptable anaerobic aquatic metabolism study may be used to fulfill data requirements for anaerobic soil metabolism.

7/Both the aerobic and anaerobic metabolism studies are required to support registration for use on drainage ditch-banks.

8/A soil column leaching study (unaged and aged soil) and an adsorption/desorption study (soil TLC) are included in this study. These studies do not fulfill current Subdivision N Guidelines. Although both studies indicate that hexazinone is mobile, the radioactivity found in leachates was not characterized; aged soils leached less than unaged soils; and soil TLC experiments were not adequately described. It is recommended that soil mobility studies be conducted as batch equilibrium adsorption/desorption studies and that these studies include the main degradation products of hexazinone.

Table A
Generic Data Requirements for Hexazinone

§158.290 Environmental Fate Footnotes (Con't)

9/Not required because the vapor pressure of hexazinone at 25 °C is below 10^{-6} mmHg.

10/The maximum application rate used was 4 lb ai/A. The study does not support registration for terrestrial nonfood uses, where the recommended application rates can be as high as 12 lb ai/A (13.5 lb ai/A to control Macartney rose in TX). In addition, the studies do not properly define the depth of leaching (in the Keyport silt loam soil, as high as 7.2% of the applied radioactivity was still detected in the 8- to 12-inch depth after 11 months). The submitted study was conducted in stainless steel cylinders using the radiolabeled material, which is an acceptable procedure.

11/The study used pellets placed by hand. Pellets contained 10% of active ingredient and were applied at a rate of 15 lb of pellets per acre (1.5 lb ai/A). The present highest recommended application rate is 6 lb ai/A for control of weeds (unspecified weeds, broadleaf weeds, and woody plants in conifer-release sites; limited to areas east of the Rocky Mountains). Therefore, data are required to support registration at the highest application rates.

12/Tank mix data requirements are not being imposed by this standard.

13/This study is reserved pending the results of the soil dissipation studies under field conditions.

14/The need for this study is triggered by the results from the confined rotational crop study.

15/Required. Drainage ditchbanks constitute an aquatic use.

16/Not required because the fish accumulation studies (165-4) did not show any accumulation of hexazinone.

17/The Agency reserves judgment on the need for these data until adequate toxicology data have been received and evaluated. The data necessary for this judgment are chronic adverse effects including neurotoxic, teratogenic, reproductive, and oncogenic effects, for which the Agency requires toxicology testing in Subdivision F of the Guidelines.

18/Soil dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work (for example, for use on potatoes or peanuts if hand harvesting will be performed).

19/The spray drift droplet spectrum and field evaluation may be done together in order to evaluate the droplet spectrum that associated with actual field use patterns.

20/There is no need for a human exposure assessment until the Toxicology Branch resolves whether hexazinone is an oncogen.

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.590 Nontarget Insect						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Contact LD_{50}	TGAI	A,B,G	No		Yes	9 Months
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B,G	No		No[1]	
141-4 - Honey Bee Subacute Feeding Study	[Reserved][2]					
141-5 - Field Testing for Pollinators	TEP	A,B,G	No		No[1]	
Nontarget Insect Testing - Aquatic Insects						
142-1 - Acute Toxicity to Aquatic Insects	[Reserved][3]					
142-2 - Aquatic Insect Life Cycle Study	[Reserved][3]					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	[Reserved][3]					
143-1 thru 143-3 - Nontarget Insect Testing - Predators and Parasites	[Reserved][3]					

Table A
Generic Data Requirements for Hexazinone

§158.590 Nontarget Insect Footnotes

1/Requirement deferred pending evaluation of data from the acute contact test.
2/Reserved pending development of test methodology.
3/Reserved pending Agency decision as to whether the data requirement should be established.

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy Thts Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TGAI	A	Partially	00104972	Yes[1]	9 Months
81-2 - Acute Dermal - Rabbit	TGAI	A	Partially	00104974	Yes[1]	
81-3 - Acute Inhalation - Rat	TGAI	A	Partially	00104975	Yes[1]	
81-4 - Eye Irritation - Rabbit	TGAI	A	Yes	00106003	No	
81-5 - Dermal Irritation - Rabbit	TGAI	A	Yes	00106004	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	No		No[2]	
Subchronic Testing						
82-1 - 90-Day Feeding						
- Rodent	TGAI	A	Yes	00104977	No	
- Nonrodent	TGAI	A	Yes	00114484	No	
82-2 - 21-Day Dermal	TGAI	A	No		Yes	12 Months
82-3 - 90-Day Dermal	TGAI	A	No		No[3]	

Table A
Generic Data Requirements for Hexazinone

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 Toxicology						
Subchronic Testing (Cont'd)						
82-4 - 90-Day Inhalation	TGAI	A	No		No[3]	
82-5 - 90-Day Neurotoxicity	TGAI	A	No		No[4]	
Chronic Testing						
83-1 - Chronic Toxicity						
- Rodent	TGAI	A	Yes	00108638	No	
- Nonrodent	TGAI	A	No		Yes	50 Months
83-2 - Oncogenicity Study						
- Rat	TGAI	A	Yes	00108638	No	
- Mouse	TGAI	A	Partially	00079203	Yes[5]	2 Months
83-3 - Teratogenicity						
- Rat	TGAI	A	Yes	403975-01	No	
- Rabbit	TGAI	A	Yes	00028863	No	
83-4 - Reproduction - Rat	TGAI	A	Partially	00108638	Yes[6]	2 Months
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A	Yes	40826201	No	
84-2 - Chromosome Aberration	TGAI	A	Yes	00130709,00131355	No	

Table A
Generic Data Requirements for Hexazinone (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.135 Toxicology						
Mutagenicity Testing (Cont'd)						
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	Yes	00130708	No	
SPECIAL TESTING						
85-1 - General Metabolism	PAIRA	A	Yes	00109237	No	

1/An additional acute oral study in female rats is required to be submitted. If the results of this study indicate a sex difference or that females may be more sensitive than males, then an additional acute dermal study in female rabbits and an acute inhalation study in female rats will be required. Otherwise, these two studies will not be required.

2/This test is required only for compounds which are organophosphate inhibitors of cholinesterase or related to such inhibitors. Hexazinone is not an organophosphate.

3/Not required for the registered use patterns.

4/Since an acute delayed neurotoxicity study is not required for hexazinone, this 90-day study is not required.

5/The registrant is required to submit all liver slides from this study to EPA for reevaluation. These slides are to be submitted to Dr. William Burnam, HED, Toxicology Branch, no later than November 30, 1988.

6/The registrant is required to submit an expanded and more detailed report or repeat the study. This additional information is to be submitted no later than November 30, 1988.

Table B
Product-Specific Data Requirements for the Manufacturing-Use Products: Hexazinone

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?1/	Timeframe Data Submission
Part 158 - Subpart C - Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	No		Yes2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes3/	6 Months
61-3 - Discussion of Formation of Impurities	MP	No		Yes4/	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes5/	12 Months
62-2 - Certification of Ingredient Limits	MP	No		Yes6/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	No		Yes7/	12 Months
Physical and Chemical Characteristics					
63-2 - Color	MP	Yes	00104969	No	
63-3 - Physical State	MP	Yes	00104969	No	

Table B

Product-Specific Data Requirements for the Manufacturing-Use Products: Hexazinone

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?[1]	Timeframe for Submission
Part 158 - Subpart C - Product Chemistry (Cont'd)					
Physical and Chemical Characteristics (Cont'd)					
63-4 - Odor	MP	Yes	00104969	No	
63-7 - Density, Bulk Density, or Specific Gravity	MP	Yes	00104969	No	
63-12 - pH	MP	No	N/A	Yes[8,9]	6 Months
63-14 - Oxidizing or Reducing Action	MP	No	N/A	Yes[8,10]	6 Months
63-15 - Flammability	MP	No	N/A	Yes[8,11]	6 Months
63-16 - Explodability	MP	No	N/A	Yes[8,12]	6 Months
63-17 - Storage Stability	MP	No	N/A	Yes[8]	15 Months
63-18 - Viscosity	MP	No	N/A	Yes[8,13]	6 Months
63-19 - Miscibility	MP	No	N/A	Yes[8,14]	6 Months
63-20 - Corrosion Characteristics	MP	No	N/A	Yes[8]	15 Months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

Table B

Product-Specific Data Requirements for the Manufacturing-Use Products: Hexazinone

Part 158 - Subpart C - Product Chemistry Footnotes

1/Although product chemistry data may have been submitted in the past, the Agency has determined that certain of these data must be resubmitted. New requirements have been introduced and previously submitted data must be updated. Therefore, many bibliographic citations for the old data are not applicable.

2/The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: The product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3/Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

4/A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/Samples from five or more representative batches must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

6/Upper and lower limits for the active ingredients and each intentionally added inert, and upper limits for each impurity present at $\geq 0.1\%$ (w/w) and each "toxicologically significant" impurity present at $< 0.1\%$ (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need to be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570-4 (Rev. 2-85).

7/Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/Physicochemical characteristics (color, physical state, odor, specific gravity, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

9/Data required if the test substance is soluble or dispersible in water.

Table B
Product-Specific Data Requirements for the Manufacturing-Use Products: Hexazinone

Part 158-Subpart C - Product Chemistry Footnotes (Cont'd)

10/Data required if the product contains an oxidizing or reducing agents.
11/Data required if the product contains combustible liquids.
12/Data required if the product is potentially explosive.
13/Data required if the product is a liquid.
14/Data required if the product is a liquid and is to be diluted with petroleum solvents.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

SUMMARY-3

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR Part 152, Subpart I. You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL REQUIRED	PLACEMENT ON LABEL PREFERRED	COMMENTS
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

Chapter 1--Environmental Protection Agency

§156.10 Labeling Requirements
previously cited as §162.10

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

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Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; If there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Hexazinone Standard

MRID	CITATION
00028733	E.I. du Pont de Nemours & Company (1976) Determination of Hexazinone Metabolite C. Undated method. (Unpublished study received Jan 21, 1980 under 352-378; CDL:099225-A)
00028863	Serota, D.G.; Wolfe, G.W.; Cole, S.S.; et al. (1980) Teratology Study in Rabbits: H-12932: Project No. 201-522. Final rept. (Unpublished study including project no. 201-521, received Mar 14, 1980 under 352-378; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099298-A)
00028866	Holt, R.F.; Baude, F.J.; More, D.W. (1979) Hexazinone Livestock Feeding Studies: Milk and Meat. (Unpublished study received Mar 14, 1980 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099298-F)
00038866	Holt, R.F. (1980) Determination of Hexazinone and Metabolite Residues Using Nitrogen Selective Gas Chromatography. Undated method. (Unpublished study received Jul 1, 1980 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099514-E)
00047164	Heitmuller, T. (1976) Acute Toxicity of H-9877 to Embryos of Eastern Oysters (Crassostrea virginica), to Grass Shrimp (Palaemonetes pugio), and to Fiddler Crabs (Uca pugilator). (Unpublished study received Jul 25, 1979 under 352-378; prepared by EG&G Bionomics, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099674-B)
00047178	E.I. du Pont de Nemours & Company (1976) 96-Hour LC50 to Bluegill Sunfish: Haskell Laboratory Report No. 409-76. (Unpublished study received Aug 29, 1978 under 352-378; CDL:099674-E)
00064260	Rhodes, R.C. (1974) Studies with Velpar Weed Killer in Water. (Unpublished study received May 7, 1975 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL: 110699-E)
00064261	Rhodes, R.C. (1974?) Decomposition of Velpar Weed Killer in Soil. (Unpublished study received May 7, 1975 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL: 110699-F)
00064262	Rhodes, R.C. (1974?) Mobility and Adsorption Studies with Velpar Weed Killer on Soils. (Unpublished study received May 7, 1975 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:110699-G)

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MRID	CITATION
00064265	Rhodes, R.C. (1974?) Four Week Residue Studies with Velpar Weed Killer and Bluegill Sunfish. (Unpublished study received May 7, 1975 under 352-378; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:110699-J)
00072663	Dudeck, S.H.; Bristol, K.L. (1980) Avian Dietary Toxicity (LC50) Study in Bobwhite Quail: Project No. 201-547. Final rept. (Unpublished study received Jan 23, 1981 under 352-387; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:244106-A)
00072664	Neary, D.G.; Douglass, J.E.; Bush, P.B.; et al. (1980) Movement of Hexazinone in Forest Watersheds after a Hand Application of Velpar: Gridball: Pellets for Site Preparation. Progress rept., Nov 1980. By U.S. Forest Service, Southeastern Experiment Station, Coweeta Hydrologic Laboratory and Univ. of Georgia, Extension Poultry Science Dept. and Institute of Ecology. ?: USFS, SE. (FS-SE-1651-26(1); available from: U.S. Government Printing Office; published study; CDL:244106-B)
00073988	Fink, R.; Beavers, J.B.; Brown, R. (1978) Final Report: Acute Oral LD50--Bobwhite Quail: Project No. 112-121. (Unpublished study received May 23, 1978 under 352-387; prepared by Wildlife International, Ltd., and Washington College, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:233989-A)
00078044	E.I. du Pont de Nemours & Company (1975?) Reports on Investigations Made with Respect to Safety: [Velpar Weed Killer]. Summary of study 095980-C. (Unpublished study received Mar 22, 1976 under 352-EX-91; CDL:095980-B)
00078047	Rhodes, R.C. (1975) Letter sent to 324 File dated Aug 12, 1975: Uptake and metabolism studies with 14:C-DPX-3674 on sugarcane in the greenhouse. (Unpublished study received Mar 22, 1976 under 352-EX-91; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:095980-E)
00079203	Goldenthal, E.I.; Trumball, R.R. (1981) Two-year Feeding Study in Mice: IRDC No. 125-026. (Unpublished study received Jul 30, 1981 under 352-378; prepared by International Research and Development Corp., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245676-A; 245677)
00093716	Piccirillo, V.J.; Carr, S.B. (1978) Final Report: Subacute Dietary LC:50 in Mallard Ducks: Project No. 201-518. (Unpublished study received Feb 1, 1979 under unknown admin. no.; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:246601-A)

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MRID	CITATION
00101574	Interregional Research Project No. 4 (1982) [Residue Studies of Hexazinone on Blueberries and Methomyl on Sugarcane]. (Compilation; unpublished study received May 17, 1982 under 2E2687; CDL:070861-A)
00104845	E.I. du Pont de Nemours & Co., Inc. (1979) Results of Tests on the Amount of Residue Remaining on Treated Crop: [Hexazinone plus Metabolites]. (Compilation; unpublished study received May 24, 1979 under 9G2214; CDL:098309-C)
00104846	Rapisarda, C. (19??) Metabolism of 14C-labeled Hexazinone in Alfalfa: Doc. No. HME 12-79. (Unpublished study received May 24, 1979 under 9G2214; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:098309-D)
00104969	E.I. du Pont de Nemours & Co., Inc. (19??) [Chemistry Data on Du Pont Velpar Weed Killer and DPX-36764!. (Compilation; unpublished study received Dec 5, 1973 under 352-EX-85; CDL:223386-A)
00104972	Dale, N. (1973) Oral LD50 Test: Haskell Laboratory Report No. 392-73. (Unpublished study received Dec 5, 1973 under 352-EX-85; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-D)
00104974	Morrow, R. (1973) Skin Absorption Toxicity ALD and Skin Irritancy Test: Haskell Laboratory Report No. 503-73. (Unpublished study received Dec 5, 1973 under 352-EX-85; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-F)
00104975	Sarver, J. (1973) One-hour Acute Inhalation Toxicity: Haskell Laboratory Report No. 305-73. (Unpublished study received Dec 5, 1973 under 352-EX-85; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-G)
00104977	Sherman, H.; Carroll, K.; Adams, L.; et al. (1973) Ninety-day Feeding Study in Rats with SYM-triazine-2,4 (1H,3H)-dione, 3-cyclohexyl-1-methyl-6-dimethylamino-[INA-3674!: Haskell Laboratory Report No. 235-73. (Unpublished study received Dec 5, 1973 under 352-EX-85; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:223386-I)
00106003	Dashiell, O.; Henry, J. (1982) Eye Irritation Test in Rabbits--EPA Pesticide Registration [INA-3674-122!: Haskell Laboratory Report No. 251-82. (Unpublished study received Jul 7, 1982 under 352-399; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:247801-A)

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MRID	CITATION
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00108638	Kaplan, A.; Frazier, C.; Adams, L.; et al. (1977) Long-term Feeding Study in Rats with ... (INA-3674): Haskell Laboratory Report No. 353-77. (Unpublished study received Aug 29, 1978 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:097323-C)
00109237	Rapisarda, C. (1980) Metabolism of 14C-labeled Hexazinone in the Rat: Document No. AMR-79-82. (Unpublished study received Jul 20, 1982 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:247874-A)
00114039	E.I. du Pont de Nemours & Co., Inc. (1978) Investigations Made with Respect to Residue Chemistry: [Velpar]. (Compilation; unpublished study received Aug 29, 1978 under 352-378; CDL: 097321-E)
00114484	Sherman, H.; Dale, N.; Adams, L.; et al. (1973) Three-month Feeding Study in Dogs with Sym Triazine-2,4(1H,3H)-dione, 3-cyclohexyl-1-methyl-6-dimethylamino-[INA-3674!: Haskell Laboratory Report No. 408-73. (Unpublished study received Apr 3, 1980 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:140051-A)
00116269	Schneider, P. (1976) 48-hour LC50 to Daphnia magna: Haskell Laboratory Report No. 262-76. (Unpublished study received Dec 30, 1977; under 352-387; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:232556-A; 235401)
00118050	E.I. du Pont de Nemours & Co., Inc. (1982) Data Supporting Amendment of Velpar Weed Killer Use on Alfalfa and Adding Velpar L Weed Killer Use on Alfalfa. (Unpublished study received Nov 15, 1982 under 352-378; CDL:248831-A)
00118509	E.I. du Pont de Nemours & Co., Inc. (1982) Product Chemistry: [Hexazinone]. (Compilation; unpublished study received Dec 17, 1982 under 352-399; CDL:071264-A)
00126127	E.I. du Pont de Nemours & Co., Inc. (1983) Results of Tests on the Amount of Residue Remaining on Treated Crop: [Hexazinone]. (Compilation; unpublished study received Feb 28, 1983 under 352-378; CDL:071438-A)

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MRID	CITATION
00130708	Ford, L. (1983) Unscheduled DNA Synthesis/Rat Hepatocytes in vitro: [INA-3674-112]: Haskell Lab Report No. 766-82. (Unpublished study received Jul 11, 1983 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:251041-A)
00130709	Vlachos, D.; Martenis, J.; Horst, A. (1982) In vitro Assay for Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Haskell Lab Report No. 768-82. (Unpublished study received Jul 11, 1983 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:251042-A)
00131355	Farrow, M.; Cortina, T.; Zito, M.; et al. (1982) In vivo Bone Marrow Cytogenetic Assay In Rats: HLA Project No. 201-573. Final rept. (Unpublished study received Jul 11, 1983 under 352-378; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:251043-A)
00138226	E.I. du Pont de Nemours & Co., Inc. (1984) Residue Chemistry Data Supporting the Use of Velpar L Weed Killer for Control of Undesirable Woody Plants in Rangeland. (Compilation; unpublished study received Apr 4, 1984 under 352-392; CDL:252954-A)
40397501	Mullin, L. (1987) Teratogenicity Study of INA-3674 in Rats: Haskell Laboratory Report No. 748-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 186 p.
40826201	Russel, J. (1977) Mutagenicity Evaluation of S-triazine-2,4(1H,3H)-dione, 3-cyclohexyl-6-dimethyl-amion-1-methyl in Salmonella Typhimurium: Haskell Laboratory Report No. 588-77. MR No. 0581-693. Revised Apr 7, 1986 by L.B. Rickard. Prepared by E.I. du Pont de Nemours and Company, Inc. Haskell Laboratory for Toxicology and Industrial Medicine. 24 p.

IV. FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO.**
PRODUCT NAME	
APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ **1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:**

☐ **2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:**

NAME OF OTHER REGISTRANT

☐ **3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:**

☐ **4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):**

☐ **5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)**

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient __________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________ and their registration number(s) is/are __________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________
(Signature)

Dated: ______________ ______________________

Reproduced from best available copy.

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________ Date ____________________________

Registration Standard for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
Part 158 Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expires 11/30/89

(To qualify, certify ALL four items)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE
	ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER
(This firm or group of firms is referred to below as "my firm".)	

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items of data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6

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